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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/577,264

05/22/2000

John S. Patton

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08/09/2006

NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 09/577,264	<b>Applicant(s)</b> PATTON, JOHN S.	
	<b>Examiner</b> David Lukton	<b>Art Unit</b> 1654	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: none.  
 Claim(s) objected to: 66.  
 Claim(s) rejected: 56, 57, 60, 63-65 and 67.  
 Claim(s) withdrawn from consideration: 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-55, 58, 59, 61, 62 and 68.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheets.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

Advisory Action

The amendment filed 8/1/06 will not be entered. The amendment proposes to expand the scope of claims 56 and 66. At the time of the final Office action, both claims required that the host be stricken with (or at risk of) osteoporosis. The amendment filed 8/1/06 proposes to simply “treat” a host, without any indication of objective. In addition, at the time of the final Office action, the claims required inhalation through the mouth; now nasal inhalation is encompassed. Accordingly, the amendment will not be entered.

Claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-68 remain pending. Claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-55, 58, 59, 61, 62 & 68 remain ~~and~~ withdrawn pursuant to the restriction/election. Claims 56, 57, 60, 63, 64, 67 remain rejected for the reasons given in the final Office action; claim 66 is objected to because of its dependence on a rejected claim.



Claims 56, 57, 60, 63-65, 67 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 recites that the composition in question “comprises” a powder. At the same time, claim 56, upon which claim 65 depends, recites that the composition in question

“consists essentially of” the indicated ingredients. Applicants have argued that the term “consists essentially of” means that the composition is limited to whatever specific ingredients are recited. According to this view, claim 65 is not properly subgeneric to claim 56, since claim 65 would permit numerous constituents to be present which are not (according to applicants) permitted by claim 56.

Claim 56 encompasses treatment of a person who is showing no signs of osteoporosis, but for whom there is a suspicion that she is vulnerable to the same. What would be the manifestations of a successful treatment for a patient who has shown no signs of osteoporosis at the time that the treatment is initiated...? In response to the foregoing, applicants have proposed a claim amendment which would overcome this particular issue; however, the amendment will not be entered.



Claims 56, 57, 60, 63, 64, 65, 67 are rejected under 35 U.S.C. §103 as being unpatentable over Wang (USP 5,011,678) in view of Neer (USP 4,698,328).

As indicated previously, Wang discloses (col 7, line 17) that PTH can be administered in aerosol form. Neer discloses (col 4, line 50+) the use of PTH(1-34) and advantages associated therewith. Thus, it would have been obvious to treat osteoporosis by inhaling PTH(1-34).

In response to the foregoing, applicants have argued that the term “consisting essentially of” is effective to exclude all compounds other than the PTH peptide, the bulking agent

and the propellant. However, applicants are not correct. As it happens, the steroids mentioned in Wang are not “essential” to the composition. If applicants have evidence that the claimed invention will fail if steroids are excluded, applicants may present evidence of the same.

The rejection is maintained.



Claims 56, 57, 60, 63, 64, 65, 67 are rejected under 35 U.S.C. §103 as being unpatentable over Wang (USP 5,011,678) in view of Morita (USP 4,656,250).

As indicated previously, Morita discloses that the peptide [Nle<sup>8</sup>, Nle<sup>18</sup>, Tyr<sup>34</sup>] PTH(1-34) has advantages over PTH(1-34). Morita does not disclose administration by inhalation; however, this is disclosed in Wang. Thus, it would have been obvious to treat osteoporosis by inhaling the PTH(1-34) analog that is disclosed in Morita.

In response to the foregoing, applicants have argued that the term “consisting essentially of” is effective to exclude all compounds other than the PTH peptide, the bulking agent and the propellant. However, applicants are not correct.

As it happens, the steroids mentioned in Wang are not “essential” to the composition. The rejection is maintained.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'D. Lukton', is positioned above the printed name.

DAVID LUKTON, PH.D.  
PRIMARY EXAMINER